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SELFAND

SERIAL NUMBER

FILING DATE

FIRST NAMED INVENTOR

D

ATTORNEY DOCKET NO.

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NAFF, D

EXAMINER

APR 3 UNIT

PAPER NUMBER

DATE MAILED:

09/04/90

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5/10/90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input checked="" type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 35-41 & 53-62 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 35-41 & 53-62 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 188.

In view of the papers filed 5/10/90 under 37 CFR 1.48(b), it has been found that this application, as filed, through error and without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R. § 1.48. The inventorship of this application has been changed by deleting Frances C. Lawyer as an inventor.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The specification fails to support the detergent being present in an amount of 0.1% to 1.0% as required by claim 56. While there is disclosure of 0.1% to 0.5% for one or more detergents and original claims 38 and 39 require two detergents,

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this does not support that 1.0% was to ~~be~~ an upper limit. When two detergents are used, the amount could have been double any amount below 05.% rather than double the upper limit of 0.5%. Moreover, when a plurality of detergents are used, the amount could be the same as when only one detergent is used.

The specification further fails to support a reaction mixture as an invention as required by claim 62. While a mixture as claimed may be formed when a reaction is carried out, this mixture exists only for a moment since the reaction begins as soon as the mixture is formed. There is inadequate support for a mixture that exists momentarily during a reaction as part of the invention.

Claims 56-62 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1, 35-39 and 53-62 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a buffer which contains substances in addition to the detergent as disclosed in the preferred embodiment. There is inadequate support that *only* a detergent will provide an operable buffer. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 38 and 37-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is unclear in not having a comma after "phenol" (line 2). Additionally, it is unclear as to how laurylethers (line 3) relate to the previous ethers and other substances required by reciting "and" before laurylethers. Claim 57 is unclear in reciting "Thermus species" since "Thermus" is a genus. To be clear in claims 58-61, the complete name of the species should be recited. Claim 62 is confusing in requiring a reaction mixture since such a mixture would be undergoing reaction and would exist as such only for an instant.

Claim 62 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The reaction mixture does not further limit the composition of claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 35-39 and 53-59 are rejected under 35 U.S.C. § 102(a) as being anticipated by the MBR product information referred to in the last paragraph of the letter of Staple of

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6/9/87 (copy supplied of information sheet entitled "DNA Polymorase").

Applicants assert that the storage buffer ~~af~~ the product of MBR resulted from information provided by applicants. However, MBR state in a Smyczek communication of 7/13/87 that the MBR product was developed independent of the information provided by applicants. The communication further indicates (page 5) that using a detergent in the buffer is obvious since it was available because of previous use, and that it is not essential for stabilization.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 40, 41 and 60-62 are rejected under 35 U.S.C. § 103 as being unpatentable over the product information of MBR (referred to above).

It would have been a matter of obvious choice and depend on individual preference and convenience to vary somewhat the pH and/or concentration of the buffer composition of MBR and/or use a species of *Thermus* other than *aquaticus* disclosed by MBR known to produce polymerase as a source of the polymerase. Using the polymerase product of MBR in a reaction mixture as required by claim 62 would have been obvious since polymerase is normally reacted in such a mixture.

Claims 1, 35-41, 53-59 and 62 are rejected under 35 U.S.C. § 103 as being unpatentable over Kaledin et al (1980) (disclosure statement) in view of Goff and if necessary in further view of Feller et al or Spiegelman.

It would have been obvious to store ^{the}polymerase of Kaledin et al in a buffer containing a nonionic detergent in view of Goff et al disclosing (col 8, line 24) that a nonionic detergent is required in recovering this enzyme and if needed in further view of Feller et al (col 5, line 7) or Spiegelman (col 6, line 25) disclosing use of a detergent-containing buffer in relation to this type of enzyme.

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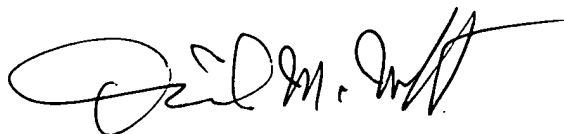
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Claims 60 and 61 are rejected under 35 U.S.C. § 103 as being unpatentable over the references as applied to claims 1, 35-41, 53-59 and 62 above, and further in view of Kaledin et al (1981) or Ruttimann et al (1985) (disclosure statement).

When using a detergent-containing buffer for polymerase as set forth above, it would have been a matter of obvious choice to use polymerase from the microorganism disclosed by Kaledin et al (1981) or Ruttimann et al (1985).

Any inquiry concerning this communication should be directed to Examiner Naff at telephone number (703) 557-2061.



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 182

Naff/th
August 30, 1990